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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,377	01/26/2005	Caroline Garey	P08555US00/BAS	7987
881 7590 07/02/2008 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314				
EXAMINER				
GABEL, GALENE				
ART UNIT		PAPER NUMBER		
1641				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/522,377

## Applicant(s)

GAREY ET AL.

## Examiner

GAILENE R. GABEL

## Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Amendment Entry***

1. Applicant's amendment and arguments filed April 14, 2008 is acknowledged and has been entered. Claims 1-15 have been amended. Claims 18 and 19 have been added. Accordingly, claims 1-15, 18, and 19 are pending and are under examination.

### ***Withdrawn Rejections or Objections***

2. All rejections / objections not reiterated herein, have been withdrawn.
3. In light of Applicant's amendment, the rejection of claims 1-9 and 11-15 under 35 U.S.C. 102(e) as being anticipated by Singh et al. (US 2002/0034827), is hereby, withdrawn.
4. In light of Applicant's amendment, the rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Singh et al. (US 2002/0034827) in view of Mandecki (US Patent 6,361,950), is hereby, withdrawn.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 1-15, 18, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, in the last line of part d) is vague and indefinite in reciting, "and the at least one secondary analyte is bound to each of the secondary supports" because it is unclear how a single "at least one" analyte can be physically bound to each individual secondary support. Does Applicant perhaps intend, "and at least one of the secondary analytes is bound to each one of the secondary supports?"

Claim 10 is ambiguous in relation to claims 9 and 18, because it is unclear how the radio frequency identification transponder is an identification means comprising one or more geometric features selected from the group consisting of shape, size, barcode, and dotcode. It appears that the RFID should be a measuring means instead.

Claim 11 is ambiguous in relation to claims 9 and 19, because it is unclear how optical identification is an identification means which is fluorescence or colour-based. It appears that the optical identification means should be a measuring means instead.

Claim 14 is ambiguous in reciting, "the tertiary analytes being capable of interacting with and the at least one primary analyte." Does the term "and" need to be removed?

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-15, 18, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Dames (WO 00/16893).

Dames et al. disclose a system comprising micromachined coded labels for use in multiparameter analysis of analytes (Abstract). The system comprises insoluble microparticle supports (microlabels) that are coded, each code carrying a different biochemical test or probe (p. 2, lines 14-17, 28-30). The insoluble microparticles are in the form of primary supports (Figure 2, #6) having bound thereto, at least one primary analyte or binding partner (Figure 2, #7) and secondary supports that can have bound thereto at least one secondary analyte or binding partner (Figure 2, #9). Both primary support and secondary support each have identification means (size, shape, and barcodes) used for identifying the support, i.e. itself. The primary supports have dimensions of 500 um or less and the secondary supports have dimensions less than or equal to the largest dimension of the primary supports (Figure 2). Each one of the primary supports and secondary supports are suspended into a fluid solution (p. 2, lines

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15-17 and line 32 to p. 3, line 4; p. 8, lines 4-6 and 15-19). The dimension of the primary and secondary supports is about 100  $\mu\text{m}$  long (less than 500  $\mu\text{m}$ ), generally in a rod shape from 40-100  $\mu\text{m}$  long. Dimensions can be 100  $\mu\text{m}$  long, 10  $\mu\text{m}$  wide, and 1  $\mu\text{m}$  thick (p. 3, line 31 to p. 4, line 5). The largest dimension of the secondary support is less than that of the primary support (Figure 2 and p. 8, lines 15-19). The system further includes a measuring means (flow-based reader system) arranged in communication with the fluid solution to detect binding and monitor interaction between analytes and binding partners by reading barcodes and identifying fluorescent test results (p. 4, lines 8-17 and p. 7, lines 5-25). The liquid suspension may also be incorporated to a solid flat substrate which comprises a main surface extending substantially in a two-dimensional plane (p. 3, lines 6-10).

7. Claims 1-15, 18, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Bruchez et al. (US 2001/0034034 A1).

Bruchez et al. disclose systems for multiparameter analysis of analytes comprising insoluble microparticle primary supports (microspheres/beads) having identification means (nanocrystals / quantum-dots and/or organic dye), i.e. microspheres in variable sizes encoded or barcoded with Q-dots or organic dye, having a primary analyte attached thereto. The system further comprises insoluble microparticle secondary supports which include therein identification means (Q-dots / labels) having secondary analytes attached thereto (Figure 1C and [0101, 0110-0111,

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0134]). The primary and secondary supports have characteristic spectral emissions which result from varying particle size and size distribution [0020-0021]. The insoluble microparticle primary supports have varying dimensions of 10  $\mu\text{m}$  and suspended in a fluid solution ([0078, 0156] and Example 12). The dimension of the primary support is less than 50  $\mu\text{m}$  (less than 500  $\mu\text{m}$ ), the dimensions of which is about 10  $\mu\text{m}$  [0302-0303]. The largest dimension of the secondary support is less than that of the primary support (1 nm to 1000 nm) [0074]. The system further includes a measuring means arranged in communication with the fluid solution for monitoring interaction between the primary and the secondary analyte by detecting the identification means of the primary support and the secondary support attached thereto ([0112, 0126-0127, 0144, 0204], Example 3 and Example 4). The liquid suspension can be placed on a solid flat substrate which comprises a main surface extending substantially in a two-dimensional plane and has tertiary analytes fixedly arranged thereon for positional identification, whereupon the tertiary analytes are capable of interacting with the at least one primary analyte (Figure 1A or 1B).

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dames (WO 00/16893) or Bruchez et al. (US 2001/0034034 A1) in view of Mandecki (US Patent 6,361,950).

Dames et al. and Bruchez et al. are discussed supra. Dames et al. and Bruchez et al. differ from the instant invention in failing to disclose that the identification means is a radio frequency identification transponder.

Mandecki discloses using solid supports having attached thereto probes or binding ligands for use in multiplexed assays, and wherein each one of the solid supports is further associated with a radio frequency identification transponder (RFID) so that data concerning the multiplexed assays are encoded into the transponders (Abstract and column 4, lines 47-60). Advantage of transponder scanner systems is that two units are not electrically connected by wire but are coupled inductively by use of electromagnetic radiation. Most importantly the narrow focus of beam of a laser light enable only one transponder to be active at a time during decoding step, hence, significantly reducing noise level (column 1 line 56 to column 2, line 2 and column 6, lines 23-50).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute RFID as taught by Mandecki into the multiplexed analytical systems as taught by Dames or Bruchez as an identification means, because RFID scanner systems have the advantage of reducing noise levels when measuring specific interactions between probes and analytes, which can add accuracy into the multiparametric systems and method of detecting analytes as taught by Dames and Bruchez.



***Response to Arguments***

9. Applicant's arguments with respect to claims 1-15, 18, and 19 have been considered but are moot in view of the new grounds of rejection.
10. No claims are allowed.
11. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
- A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **GAIENE R. GABEL** whose telephone number is

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(571)272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/  
Primary Examiner, Art Unit 1641

June 25, 2008